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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,979	05/10/2000	THOMAS J. HIGGINS	33-00	4903

23713 7590 01/29/2003

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/508,979	HIGGINS ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-6,8,11-57,64,65,67-69,86-94 and 96-101* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-6, 8, 11-57, 64-65, 67-69 and 86-94 and 96-101* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *21* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Prosecution Application

The request filed on November 13, 2002, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/508979 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 1, 21, 28, 33, 38, 42, 47 and 52 are newly amended.

Claim 101 is newly added.

Claims 1-2, 4-6, 8, 11-57, 64-65, 67-69 and 86-94 and 96-101 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-6, 8, 11-57, 64-65, 67-69 and 86-94 and 96-101 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to methods of modifying the content or composition of a metabolite in the storage organ of a plant, said method comprising (i) expressing in the storage organ a chimeric gene comprising a nucleotide sequence encoding a sulfur-rich protein, (ii) determining

the composition or content or content and composition of a metabolite in said storage organ, and (iii) selecting a plant having a modified content or composition or content and composition, of said metabolite in the storage organ thereof". The claims are also drawn to plants produced by said methods.

The limitation "(iii) selecting a plant having a modified content or composition or content and composition, of said metabolite in the storage organ thereof" does not find support in the specification as filed, and thus constitutes new matter.

Claims 1-2, 4-6, 8, 11, 14-27, 65, 67-69, 86-87 and 101 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to methods of modifying the content or composition of a metabolite in the storage organ of a plant, said method comprising (i) expressing in the storage organ a chimeric gene comprising a nucleotide sequence encoding a sulfur-rich protein, (ii) determining the composition or content or content and composition of a metabolite in said storage organ, and (iii) selecting a plant having a modified content or composition or content and composition, of said metabolite in the storage organ thereof". The claims are also drawn to plants produced by said methods.

The claims do not recite the specific identity of any particular nucleotide sequence encoding any particular sulfur-rich protein which modifies the content or composition or content and composition, of a metabolite in the storage organ of a plant transformed therewith. Absent

reference to the particular identity of the sulfur-rich protein encoded by the nucleotide sequence a critical element of the claimed invention remains undefined, such that the invention is not adequately described. In contrast, the specification only describes one method for making a variety of specific changes the content or composition of a variety of specific metabolites in the seed of transgenic lupin, pea, chickpea and rice plants, said method comprising transforming the plants with a nucleotide sequence encoding sunflower seed albumin (pages 27-42). While the specification indicates that other nucleotide sequences encoding other sulfur-rich proteins from other sources may be used to practice the claimed method, no guidance is presented with respect to the characterization of these sequences.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lily and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the sequences encoding sulfur-rich proteins, any method of using them

would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

Claims 1-2, 4-6, 8, 11-57, 64-65, 67-69 and 86-94 and 96-101 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing the total protein nitrogen content in the seed of a pea, chickpea or rice plant, said method comprising (i) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin operably linked to a promoter sequence capable of conferring expression in a seed, and (ii) determining the content of total protein nitrogen in said seed, a method of increasing the fiber content in the seed of a pea plant, said method comprising (i) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin and (ii) determining the content of fiber in said seed, a method of decreasing the fiber content, decreasing the soluble and insoluble non-starch polysaccharide components of fiber, and increasing the lignin component of fiber, in the seed of lupin a plant, said method comprising (i) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin and (ii) determining the content or composition of fiber in said seed, a method of increasing the oil content, and increasing the stearic acid and oleic acid fatty acid components of oil, and decreasing the myristic acid, palmitic acid, linoleic acid, linolenic acid, arachidic acid, gadoleic acid, behenic acid, erucic acid and lignoceric acid fatty acid components of oil, in the seed of lupin a plant, said method comprising (i) expressing in the seed

a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin and (ii) determining the content of oil in or the fatty acid composition of said seed, a method of decreasing the oil and starch content in the seed of a pea plant, said method comprising (i) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin and (ii) determining the content of oil or starch in said seed, a method of increasing the amino acids aspartic acid, threonine, serine, glutamic acid, proline, glycine, alanine, valine, isoleucine, leucine, arginine, cysteine and methionine in the seed of a pea plant, said method comprising (i) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin and (ii) determining the amino acid composition of said seed, and a method of increasing the amino acids aspartic acid, threonine, serine, glutamic acid, proline, glycine, alanine, valine, isoleucine, leucine, arginine, cysteine, methionine, tyrosine, phenylalanine and lysine in the seed of a chickpea plant, said method comprising (i) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin and (ii) determining the amino acid composition of said seed, does not reasonably provide enablement for methods of modifying the content or composition of any metabolite in any storage organ of any plant by expressing in the storage organ a chimeric gene comprising a nucleotide sequence encoding any sulfur-rich protein operably linked to any promoter. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to methods of modifying the content or composition of a metabolite in the storage organ of a plant, said method comprising (i) expressing in the storage organ a

chimeric gene comprising a nucleotide sequence encoding a sulfur-rich protein, (ii) determining the composition or content or content and composition of a metabolite in said storage organ, and (iii) selecting a plant having a modified content or composition or content and composition, of said metabolite in the storage organ thereof". The claims are also drawn to plants produced by said methods.

In general, the specification discloses a method for making changes in the content or composition of a variety of specific metabolites in the seed of transgenic lupin, pea, chickpea and rice plants by transforming the plants with a nucleotide sequence encoding sunflower seed albumin. More specifically, the specification discloses that transforming lupin plants with a nucleotide sequence encoding sunflower seed albumin results in an increase in the content of lignin, oil, stearic acid and oleic acid fatty acids, and a decrease in myristic acid, palmitic acid, linoleic acid, linolenic acid, arachidic acid, gadoleic acid, behenic acid, erucic acid and lignoceric acid fatty acids, as well as a decrease in total fiber and soluble and insoluble non-starch polysaccharide components of fiber, in the seed of transgenic lupin plants as compared to nontransgenic control plants (pages 28-29), that transforming pea plants with a nucleotide sequence encoding sunflower seed albumin results in an increase in the total protein nitrogen content, an increase in the content of the amino acids aspartic acid, threonine, serine, glutamic acid, proline, glycine, alanine, valine, isoleucine, leucine, arginine, cysteine and methionine, an increase in fiber content, and a decrease in starch and oil content, in the seed of transgenic pea plants as compared to nontransgenic control plants (pages 29-32), that transforming chickpea plants with a nucleotide sequence encoding sunflower seed albumin results in an increase in the total protein nitrogen content, and an increase in the content of the amino acids aspartic acid,

threonine, serine, glutamic acid, proline, glycine, alanine, valine, isoleucine, leucine, arginine, cysteine, methionine, tyrosine, phenylalanine and lysine, in the seed of transgenic chickpea plants as compared to nontransgenic control plants (pages 37-38), and that transforming rice plants with a nucleotide sequence encoding sunflower seed albumin results in an increase in the total protein nitrogen content in the seed of transgenic rice plants as compared to nontransgenic control plants (page 41).

The specification does not disclose methods for making specific changes in the content or composition of specific metabolites in a storage organ other than a seed, and the specification does not disclose the effect of transforming a plant with a nucleotide sequence encoding a sulfur-rich protein other than sunflower seed albumin, such as a nucleotide sequence encoding brazil nut albumin, for example. The specification does not provide sufficient guidance for one skilled in the art to determine which non-exemplified nucleotide sequences to use and how to express them, because the specification discloses the effects of only one nucleotide sequence from one source encoding only one sulfur-rich protein.

Guidance for making and using the claimed invention is necessary for enablement because the ability of a nucleotide sequence encoding any sulfur-rich protein from any source to modify the content or composition of any metabolite in any storage organ of any species of transgenic plant is unpredictable. The ability of a nucleotide sequence encoding a sulfur-rich protein to modify the content or composition of a metabolite in a storage organ of a transgenic plant would be differentially affected by the particular protein expressed, as sulfur-rich proteins vary in their composition and function. For example, Molvig et al. (August 1997, Proc. Natl. Acad. Sci. USA, Vol. 94, pages 8393-8398, Applicant's IDS) teach that the seed of *Lupinus*

angustifolius plants transformed with a nucleotide sequence encoding the sulfur-rich protein sunflower seed albumin exhibit increased levels of the amino acid methionine, decreased levels of the amino acid cysteine, but no change in the level of other amino acids, as compared to nontransgenic control plants (page 8396 Table 2). In contrast, Muntz et al. (1997, Sulfur Metabolism in Higher Plants, ed. W.J. Cram, pages 71-86, Applicant's IDS) teach that the seed of *Vicia narbonensis* plants transformed with a nucleotide sequence encoding the sulfur-rich protein brazil nut albumin exhibit increased levels of the amino acid methionine, increased levels of the amino acid arginine, but no change in the level of cysteine, as compared to nontransgenic control plants (page 81 Figure 7). The ability of a nucleotide sequence encoding a sulfur-rich protein to modify the content or composition of a metabolite in a storage organ of a transgenic plant would also require the expression of that sequence in the storage organ, as the ability of the sulfur-rich protein to modify the content or composition of a metabolite in the storage organ would be dependent on the presence of the sulfur-rich protein in the storage organ. The ability of a nucleotide sequence encoding a sulfur-rich protein to modify the content or composition of a metabolite in a storage organ of a transgenic plant would, in addition, be differentially affected by the content and composition of the cellular environment in which the protein is expressed, as the content and composition of the cellular environment varies between storage organ types and between plant species. For example, Muntz et al. (1997, Sulfur Metabolism in Higher Plants, ed. W.J. Cram, pages 71-86, Applicant's IDS) teach that among legumes, the ratio of vicilin-like 7S to legumin-like 12S storage proteins in seeds varies, (page 72 2nd full paragraph).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, it would require undue experimentation for one skilled in the art to determine which

nonexemplified nucleotide sequences encoding sulfur-rich proteins to use, and in which storage organs and species of plant to express the sequences, in order to obtain the specific metabolite modifications claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-6, 8, 21, 28, 31, 32, 33, 38, 42, 46, 47, 50, 51, 52, 56, 57, 88, 89, 90, 91, 93, 94 and 101, and claims 2, 4, 11-20, 22-27, 30, 34-37, 39-41, 43-45, 48-49, 53-55, 64-65, 67-69, 86-87, 92 and 96-100 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 6, 28, 33, 42, 47, 52, 89, 91, 94 and 101 are indefinite in the recitation of "modifying" and "modified". It is unclear in what way the content or composition of a metabolite in the storage organ of a plant is modified, as the content or composition of a metabolite may be modified in a variety of different ways, such as by a total increase in the content, a total decrease in the content, an addition or subtraction to the content, and addition or subtraction to the composition, an increase in one or more components of the composition, a decrease in one or more components of the composition, etc. Additionally, "modifying" and "modified" are relative terms lacking a comparative basis.

Claims 5, 8, 21, 31, 46, 51, 57, 88, 90 and 93 are indefinite in the recitation of "increasing" and "increased". "Increasing" and "increased" are relative terms lacking a comparative basis.

Claims 8, 32, 38, 50, 56, 90, 92 and 93 are indefinite in the recitation of "decreasing" and "decreased". "Decreasing" and "decreased" are relative terms lacking a comparative basis.

Claims 1 and 101 are indefinite in the recitation of "oil (fatty acid)". It is unclear whether the use of parentheses is intended to limit "oil" to fatty acids only.

Claim 5 is indefinite in the recitation of "total" protein nitrogen. There is insufficient antecedent basis for "total" in claim 1 from which claim 5 depends.

Claim 57 is indefinite in the recitation of "content". There is insufficient antecedent basis for "content" in claim 52 from which claim 57 depends.

Claim 101 is indefinite because it is unclear what happens to "at least one of said metabolites" in the selected plant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-6, 8, 11-17, 19-23, 25-26, 28-31, 33-40, 42-44, 47-50, 52-57, 64-65, 67-69 and 86-94 and 96-100 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Molvig et al. (August 1997, Proc. Natl. Acad. Sci. USA, Vol. 94, pages 8393-8398, Applicant's IDS).

The claims are drawn to methods of modifying the content or composition of a metabolite in the storage organ of a plant, including a lupin plant, said method comprising (i) expressing in the storage organ, including a seed, a chimeric gene comprising a nucleotide sequence encoding a sulfur-rich protein, including sunflower seed albumin (ii) determining the composition or content or content and composition of a metabolite in said storage organ, and (iii) selecting a plant having a modified content or composition or content and composition, of said metabolite in the storage organ thereof". The claims are also drawn to plants produced by said methods.

Molvig et al. teach a method of modifying the amino acid composition of the seed of a lupin plant, said method comprising (i) expressing in the seed a chimeric gene comprising a nucleotide sequence encoding sunflower seed albumin, and (ii) determining the amino acid content and composition of the seed (page 8393, column 2, fourth full paragraph through page 8394; page 8395, column 1, paragraph 1; page 8396 Table 1).

While Molvig et al. teach the claim limitations of modifying the content or composition of a metabolite in the storage organ of a plant, including a lupin plant, said method comprising (i) expressing in the storage organ, including a seed, a chimeric gene comprising a nucleotide sequence encoding a sulfur-rich protein, including sunflower seed albumin, and (ii) determining the composition or content or content and composition of a metabolite in said storage organ, as well as a transgenic plant produced by said method, Molvig et al. is silent with respect to the claim limitations directed to specific metabolites other than amino acids, and with respect to the claim limitation directed to the step of selecting a plant having a modified content or composition or content and composition, of said metabolite in the storage organ thereof. The Examiner is unable to determine whether the prior art disclosure possesses the unrecited

characteristics or properties, as the USPTO does not have sufficient facts to determine whether the claimed methods and products and the methods and products of the prior art are inherently the same. The Examiner also cannot conclude that the subject matter of the claim would have been obvious since it cannot determine whether the claimed methods and products and the methods and products of the prior art differ. The Examiner is not in a position to make either a conclusion of "inherency/anticipation" or "obviousness", since the record does not allow one to determine if and how the claimed subject matter differs from the prior art. With these conditions, where the method or product by process seems to be identical except that the prior art is silent with respect to certain characteristics or properties claimed, the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention (see *In re Best*, 195 USPQ 430, 433 (CCPA 1977)).

Claim Rejections - 35 USC § 103

The rejection of claims 1-2, 4-6, 8, 11-57, 64-65, 67-69 and 86-94 and 96-100 solely under 35 U.S.C. 103(a) as being unpatentable over Molvig et al. (August 1997, Proc. Natl. Acad. Sci. USA, Vol. 94, pages 8393-8398, Applicant's IDS) set forth in the office action mailed March 14, 2002 is withdrawn upon further consideration.

Applicant's arguments filed November 13, 2002 have been fully considered but are not considered germane to the current rejection set forth above under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Molvig et al. (August 1997, Proc. Natl. Acad. Sci. USA, Vol. 94, pages 8393-8398, Applicant's IDS), as the current rejection does not allege either anticipation under 35 U.S.C. 102(b), or obviousness under 35

U.S.C. 103(a), but merely asserts that the Office is unable to determine either anticipation or obviousness on the basis of the evidence currently before the Examiner.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
January 27, 2003

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600